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THE PROPRIETARY ASSOCIATION

October 25, 1982

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Dockets Management Branch
Food and Drug Administration
HFA-305
Room 4-62
5600 Fishers Lane
Rockville, Maryland 20857

Re: Skin Bleaching Drug Products for Over-The-Counter Human Use: Tentative
Final Monograph, 47 Fed. Reg. 39108 (1982) [Docket No. 78N-0065]

Dear Sir:

The above-captioned Notice of Proposed Rulemaking (TFM), which was issued after a consideration of the report and recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products, and public comments on an ANPR based on those recommendations, appeared in the September 3, 1982 Federal Register. Written comments were requested by November 2, 1982.

These comments are filed on behalf of The Proprietary Association, a 101-year-old trade association, the active members of which are engaged in the manufacture and distribution of nonprescription, over-the-counter medicinal products. Members of the Association are subject to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) and are interested in and affected by this TFM.

These comments are not intended to supersede any comments that may be filed by members of the Association.

General Comments on OTC Review in General

1. Legal Status of Monographs

The Association notes its continuing position that Monographs issued under the OTC Drug Review are interpretive, as opposed to substantive, regulations. As to this point, the Association herein incorporates by reference: (a) its March 4, 1972 comments on the Proposed Procedures for Classification of Over-The-Counter Drugs; and (b) its June 4, 1973 comments on the Proposed Antacid Monograph.

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2. Exclusivity Policy

The Association also notes its continuing position that FDA cannot legally and should not, as a matter of policy, prescribe exclusive lists of terms from which indications for use for OTCs must be drawn and prohibit alternative OTC labeling terminology to describe such indications which is truthful, not misleading, and intelligible to the consumer.

The Association's views on this subject were presented in oral and written testimony submitted to FDA in connection with the September 29, 1982 FDA hearing on the exclusivity policy.

3. The Agency requires the statement of identity of these products to use the words "Skin Bleaching Agent" or "Skin Lightener." The Proprietary Association believes that other terminology could also be used which would also accurately describe the action of these products for the following reasons.

The need for flexibility is especially significant in this case where these products are used by different ethnic groups who use different terminology to describe their function.

The Agency's position is stated (p. 39111) that: "The agency believes that consumers are familiar with the terms "Skin Bleaching" and "Skin Lightening" and that the use of these terms, along with the indications for the product contained in Section 358.50(b) (Indications Statement), accurately describe for consumers the pharmacologic results to be obtained from using these products."

The Proprietary Association submits that a number of other terms such as "Skin Tone Cream", "Fade Cream" or "Depigmenting Cream," accurately describe for consumers the pharmacologic results to be obtained with these products. These terms, and others which are truthful and not misleading, should therefore also be allowed as statements of identity.

In discussing the use of the word "tone" on page 39111, the agency states that it "believes that substantial confusion can be prevented by excluding the word 'tone' from labeling."

In fact, the historic usage of the term "Skin Tone Cream" by many black consumers to describe this type of product indicates that such consumers understand and are not misled by the use of this term.

4. The Agency objects to statements that refer to making skin color "even" (p. 39111) and states that "in fact, Hydroquinone would exert its action on all pigment."

The Association believes that use of the term "even" in referring to these products' actions on skin color is meaningful, truthful and not misleading to consumers for the following reasons:

The directions state that the product should be applied to the affected (darkened) areas and therefore the action of the products would be to lighten the dark areas; hence producing an even tone. Evenness of skin color is the benefit required from these products and this term should therefore be allowed in describing the action of the products.

The literature does not support a conclusion that hydroquinone exerts its action on all pigment. In fact, Arndt and Fitzpatrick (ref. 1) state that "the effectiveness of hydroquinone appeared to depend on the type of melanosis." This indicates that hydroquinone does not exert its effect equally on all pigment.

The use of the word "even" in statements such as "Even skin tone by lightening darkened areas" should therefore be allowed.

5. The agency proposes a statement in the directions such as "Lightening effect of this product may not be noticeable on dark skin."

The Proprietary Association objects to this on the following grounds:

The statement is overly broad and is potentially confusing to consumers in that it may be construed to mean that hydroquinone will not lighten areas of darkened skin.

The basis used by FDA for this statement is the paper by Spencer (ref. 2) which compares the depigmenting action of hydroquinone on hyperpigmented areas on white males with the effect on normal pigmentation of black males, while the normal use of this product is for lightening hyperpigmented areas, not normal pigmentation. The paper does not support or justify the agency's requirement for the inclusion of the statement "Lightening effect of this product may not be noticeable on dark skin." In addition, there is nothing in the record to support the belief that hydroquinone will not lighten hyperpigmented areas on dark skin.

6. The Proprietary Association believes that there should be a reference made in the directions to the continued use of hydroquinone products to prevent the recurrence of hyperpigmented marks where such marks have been lightened through the use of these products.

There are numerous references in the record (ref. 1, 2 and 3) which indicate that in some cases hyperpigmentation will recur upon the cessation of successful treatment and in these cases there should be a provision in the directions for continued use of the product beyond the three months identified by the agency.

7. The Agency requires a warning that the product should "not be used by children under 12 unless directed by a doctor" as well as directions for use by children under 12 years of age to read "do not use unless directed by a doctor."

The Proprietary Association submits that the directions for use by children under 12 should be removed as redundant.

8. For products containing a sunscreen, the agency would require a statement in the directions which would state: "Sun exposure should be limited by using a sunscreen agent, a sun blocking agent or protective clothing to cover bleached skin after treatment is completed in order to prevent darkening from recurring."

For products not containing a sunscreen, the agency would require a statement in the directions which would state: "Sun exposure should be limited by using sunscreen agent, a sun blocking agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring."

The Proprietary Association submits that these statements are not clear or concise and, because they do not differ significantly from each other, could be combined in a statement such as: "Limit exposure to the sun to prevent darkening from recurring" which would be useful information to users of all products including those with and without sunscreens in combination with Hydroquinone.

The Association appreciates the opportunity to submit these comments.

Sincerely,

THE PROPRIETARY ASSOCIATION

James D. Cope
President

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